The Examiner required that Applicants elect a single species from the SEQ ID NOs disclosed in (a), and a single species from the SEQ ID NOs encompassed by (b) (*see*, Office Action of July 1, 2004)

As set forth in the response of August 25, 2004, Applicants again provisionally elect, with traverse, the species of SEQ ID NO: 28 for (a), and the species of SEQ ID NO: 38 from the sequences encompassed by (b).

Election of SEQ ID NO:28 reads on claims 1, 8-20, 25, 27-28, 30, 42, and 44. Election of SEQ ID NO: 38 reads on claims 2, 4, 6-20, 22, 25, 27, 28, 30, 43 and 45. If the Examiner has any questions regarding the election or the claims that read on the elected species, she is invited to call the Attorney of record.

Applicants' substantive arguments in support of their traversal of the species election requirement are the same as those presented in the Response of August 25, 2004, and are set forth below as a courtesy to the Examiner.

At the outset, it is noted that when the instant application was originally filed, the Examiner who first examined this case (Examiner Joyce Tung) restricted the claims into three groups (*see*, Appendix A). Group I consisted of claims drawn to a synthetic oligonulceotide complementary to a portion of the 5' untranslated region of the hepatitis C virus, classified in class 536, subclass 23.1 or 24.3. Group I claims consisted of essentially the same claims as those that are currently pending in the instant application. The previous Examiner did not require a species election, either in making the Restriction Requirement, or throughout the prosecution of the application. Thus, Applicants respectfully contend the United States Patent and Trademark Office has previously determined (implicitly) that it would not pose an undue burden to examine the currently pending claims without a species election. Furthermore, Applicants respectfully assert that it would also not be unduly burdensome for the Examiner to search all the claimed species of synthetic oligonucleotides in the instant application as they all relate to the hepatitis C virus.

However, even if the Examiner were to consider the examination of the present claims to be unduly burdensome, Applicants note that MPEP § 803.04 states that "the Commissioner has

decided *sua sponte* to...permit a ***reasonable number*** of nucleotide sequences to be claimed in a single application...(and that)....it has been determined that normally ***ten*** sequences constitute a reasonable number for examination purposes" (emphases added). This section of the MPEP goes on to state that "in some ***exceptional*** cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten" (emphasis added).

The instant Restriction Requirement states only that "the large number of individual sequences encompassed by the claims necessitates this requirement, as the claims as now written cannot be searched and examined without posing a serious burden."

Applicants respectfully note that, first, the synthetic oligonulceotide sequences in question are only about 12-32 nucleotides in length and are readily searchable using the computer algorithms and sequence databases available to the P.T.O., so that it is unclear upon what basis the assertion that the search poses a serious burden rests. Applicants further note that, even if the search were "complex" in nature, MPEP § 803.04 does not state that this is an issue in examining multiple sequences, rather it states that the complexity of the claimed material may be an issue in some exceptional cases, however the sequences claimed are not complex and a justification for their exceptional treatment has not been presented. Furthermore, Applicants note that the mere fact that the sequences "each have a unique nucleotide sequence" is not dispositive to whether it would be an undue burden to examine them together. This is particularly true in the instant case where a simple search for all possible hepatitis C virus antisense sequences could be conducted simply and efficiently by using straightforward search strings using the known hepatitis C nucleotide sequence. In view of these points, Applicants respectfully urge reconsideration of the species election requirement and withdrawal of the requirement to elect a single synthetic oligonucleotide sequence from each of (a) and (b) described above.

CONCLUSION

In summary, Applicants have provisionally elected, with traverse, the species of **SEQ ID NO: 28** for (a) and the species of **SEQ ID NO: 38** for (b).

Applicants respectfully urge reconsideration and withdrawal of the species election requirement. Further and favorable consideration on the merits of the claims of record is also respectfully requested at this time.

No additional fees are believed to be due in connection with this correspondence; however, if any fees are due, please charge the payments due to our Deposit Account No. 08-0219.

If a telephone interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,

Dated: November 22, 2004

Ann-Louise Kerner, Ph.D.
Reg. No. 33,523

WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel.: (617) 526-6192
Fax: (617) 526-5000

APPENDIX A

A copy of the Restriction Requirement made in this case when it was originally filed.

EXPRESS MAIL LABEL NO. EV225199282US
DATE OF DEPOSIT 11/22/2004

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 11

Application Number	08/887,505
Filing Date	07/02/1997
First Named Inventor	Kilkulskie
Art Unit	1634
Examiner Name	Diana B. Johannsen
Attorney Docket Number	HYZ-040CIP

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  - Postcard
  - Response to Notice of Non-Responsive Amendment

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Wilmer Cutler Pickering Hale and Dorr LLP		
Signature	Ann-Louise Kerner		
Printed name	Ann-Louise Kerner, PhD.		
Date	11/22/2004	Reg. No.	33,523

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as ~~express~~ mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Jason Gregoire		
Typed or printed name	Jason Gregoire	Date	11/22/2004

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/887,505	07/02/97	KILKUSKIE R	HYZ-040CIP

HM31/0910

HALE AND DORR
60 STATE STREET
BOSTON MA 02109

EXAMINER	
TONG, J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/10/98

BEST AVAILABLE COPY

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Resp. to Restr. Req. due 10/10/98
Bar 3/10/99

Docketed
JGS
9-23-98

Office Action Summary

Application No.	Applicant(s)
08/887,505	Kilkuskie et al.
Examiner	**Group Art Unit**
Joyce Tung	1634

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-41* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-41* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31, drawn to an synthetic oligonucleotide complementary to a portion of the 5' untranslated region of hepatitis C virus, classified in class 536, subclass 23.1 or 24.3.

II. Claims 32-37, drawn to a pharmaceutical composition, method of inhibiting and treating hepatitis C virus, classified in class 514, subclass 44.

III. Claims 38-41, drawn to a method of detecting hepatitis C virus and kit including all reagents, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group II is drawn to a pharmaceutical composition, method of inhibiting and treating which can be done with an antibody, while Group I can be used in nucleic acid mapping.

4. Inventions Group I and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group III can be practiced with a different oligonucleotides, while Group I can be used in nucleic acid mapping.

5. Inventions Group II and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention, Group II is drawn to a method of treating hepatitis C virus, while Group III is drawn to a method of detecting hepatitis C virus.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7 Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 6:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group1634 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

September 4, 1998

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

9/8/98